Pride®
Mobility Products Corp.

182 Susquehanna Ave
Exeter, PA 18643
570-655-5574
FAX 655-2990

K111739

AUG 12 2011

Exhibit 1
510(k) Summary
Pride Mobility Products Corporation
Kids ROCK 3 Chair

Submitter's Name & Address:
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-2990

Contact Person:
Kimberly Blake
Assistant Manager, Regulatory

Date Prepared:
6/17/2011

Name of Device and Proprietary Name:
Kids ROCK 3 Chair / Pride Mobility Products Corporation

Common or Usual Name:
Mechanical Wheelchair

Classification Name:
Physical Medicine / Mechanical Wheelchair

Product Code:
IOR

Comparison to Predicate Devices:

The Kids ROCK 3 Chair is substantially equivalent to the Pride Mobility Litestream 500E (K042444) when comparing performance, maneuverability, stability, and structure. The performance characteristics are similar to achieve the same intended use functions that enable the device to maintain optimum stability without hindering performance.

The major differences between the Kids ROCK 3 Chair and the Litestream 500E (K042444) are in the seating. The Kids ROCK 3 Chair seating is adjustable to allow for growth as the user moves through various stages of life and offers a manual tilting feature.

Please refer to Exhibit 4 for specific product descriptions and comparison of the Kids ROCK 3 Chair to the cleared Litestream 500E (K042444).

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Device Description:

The Kids ROCK 3 Chair is a Mechanical Wheelchair that offers adjustable and customizable seating and positioning to meet the needs of a growing client. The Reaction Dynamic Seating System allows a user the freedom to move into flexion or extension in the chair while maintaining proper positioning and support.

Intended Use:

The intended use of the Pride Mobility Products Corporation Kids ROCK 3 Chair is to provide mobility to persons limited to a seated position.

Non-Clinical Testing:

ANSI/RESNA WC19 Wheelchairs Used as Seats in Motor Vehicles
ISO 7176-19 Wheeled Mobility Devices for Use in Motor Vehicles
ISO 7176-15 Requirements for information disclosure, documentation, and labeling
ISO 7176-8 Requirements and test methods for static, impact, and fatigue strengths
ISO 7176-1 Determination of static stability
ISO 7176-7 Measurement of seating and wheel dimensions
ISO 7176-5 Determination of overall dimensions, mass, and turning space
ISO 7176-3 Determination of efficiency of brake
Manually propelled wheelchairs
Technical Aids for Disabled Persons
Fabric and Foam Testing

Discussion of Clinical Testing Performed:

N/A

Conclusions:

The Kids ROCK 3 Chair has the same intended use and similar technological characteristics as the Litestream 500E (K042444). Moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Kids ROCK 3 Chair is substantially equivalent to the Litestream 500E (K042444).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pride Mobility Products Corporation
% Ms. Kimberly Blake
Assistant Manager, Regulatory
182 Susquehanna Avenue
Exeter, PA 18643

AUG 12 2011

Re: K111739
Trade/Device Name: Kids ROCK 3 Chair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: July 11, 2011
Received: July 14, 2011

Dear Ms. Blake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Pride®
Mobility Products Corp.

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Exhibit 3

Indications for Use

510(k) Number (if known): K

Device Name: Kids ROCK 3 Chair

Indications for Use: The intended use of the Kids ROCK 3 Chair is to provide mobility to persons limited to a seated position.

Prescription Use ____X____ **AND / OR** **Over-The-Counter Use** __X__
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111739